True™ BAV Balloon Valvuloplasty Catheter

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
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Contact:	Aaron Conovaloff, Regulatory Affairs Associate
Date	July 21, 2014

Subject Device Name:

Device Trade Name:	**True™ BAV Balloon Valvuloplasty Catheter**
Common or Usual Name:	Balloon Aortic Valvuloplasty (21 CFR 870.1250, Product Code OZT)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

- True Dilatation™ Balloon Valvuloplasty Catheter (K133569; cleared December 20, 2013)
- Vida™ PTV Dilatation Catheter (K131002, cleared July 2, 2013)

Device Description:

The True™ BAV Balloon Valvuloplasty Catheter is a high performance balloon catheter consisting of an over-the-wire catheter with a balloon fixed at the distal tip. The proprietary, non-compliant, low profile balloon is designed to provide consistent balloon diameters and lengths. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The coaxial catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the valve. The over-the-wire catheter is compatible with .035" guidewire and is available in 100 cm working length. The proximal portion of the catheter includes a female luer-lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen. Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A re-wrapping tool is also provided on the catheter shaft. This product is not manufactured with any latex.

Attribute	True™ BAV Balloon Valvuloplasty Catheter Product Offering
Balloon Diameter (mm)	18, 20, 22, 24, 26
Balloon Length (cm)	4
Catheter Shaft Length (cm)	100
Introducer Sheath Compatibility by Balloon Diameter (mm)	8F: 18 mm 9F: 20 mm 10F: 22 mm, 24 mm 12F: 26 mm

Indications for Use of Device:

The True™ BAV Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Comparison of Indications for Use to Predicate Devices:

The indications for use statement for the True™ BAV Balloon Valvuloplasty Catheter does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices. Therefore, the subject device, the True™ BAV Balloon Valvuloplasty Catheter, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The True™ BAV Balloon Valvuloplasty Catheter has the following similarities to the predicate device, the True Dilatation™ Balloon Valvuloplasty Catheter (clearance to market via K133569 on December 20, 2013):

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Same sterility assurance level and method of sterilization

The True™ BAV Balloon Valvuloplasty Catheter has the following similarities to the predicate device, the Vida™ PTV Dilatation Catheter (clearance to market via K131002, on July 2, 2013):

- Same operating principle
- Same fundamental scientific technology
- Same packaging materials and configurations
- Same sterility assurance level and method of sterilization

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate devices, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Visual Inspection

- Balloon Distensibility

The following *in vitro* tests were leveraged from the predicate Vida™ PTV Dilatation Catheter:

- Tip Length
- Balloon Outer Diameter (i.e. Diameter and Profile Test)
- Balloon Working Length
- Catheter Shaft Outer Diameter
- Catheter Shaft Inner Diameter
- Tip Visibility
- Catheter Shaft Visibility
- Marker Band Visibility
- Tip Morphology
- Tip Tensile (i.e. Tip Pull and Torque Test, and Bond Strength Test)
- Balloon to Shaft Tensile
- Hub to Shaft Tensile
- Catheter Shaft Elongation
- Balloon Nominal (Operating) Pressure
- Rated Burst Pressure (i.e. Balloon Minimum Burst Strength)
- Balloon Burst Mode
- Fatigue (i.e. Repeated Balloon Inflation)
- Catheter Shaft Leaks (i.e. Catheter Body Maximum Pressure Test)
- Catheter Shaft Burst (i.e. Catheter Body Maximum Pressure Test)
- Media Interaction (i.e. Balloon Preparation Test)
- Catheter Shaft Length
- Trackability
- Inflation/Deflation Time (i.e. Balloon Inflation/Deflation Test, and Balloon Inflatability Test)
- Marker Band Alignment
- Sheath Compatibility
- Equipment Interface
- Visual Inspection of Packaging

- Dye Penetration
- Pouch Tensile Strength

The results from these tests demonstrate that the technological characteristics and performance criteria of the True™ BAV Balloon Valvuloplasty Catheter are substantially equivalent to the predicate devices, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusions:

The subject device, the True™ BAV Balloon Valvuloplasty Catheter, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The True™ BAV Balloon Valvuloplasty Catheter is substantially equivalent to the legally marketed predicate devices, the True Dilatation™ Balloon Valvuloplasty Catheter and the Vida™ PTV Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Bard Peripheral Vascular, Inc.
Dr. Aaron Conovaloff
Regulatory Affairs Associate
1625 West 3rd Street
Tempe, Arizona 85281

Re: K141985
Trade/Device Name: True BAV Balloon Valvuloplasty Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: July 21, 2014
Received: July 22, 2014

Dear Dr. Conovaloff:

This letter corrects our substantially equivalent letter of September 18, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141985

Device Name: True™ BAV Balloon Valvuloplasty Catheter

Indications for Use: The True™ BAV Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)